DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

RB 12/30/96

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Certified/Return Receipt Requested

December 20, 1996

WARNING LETTER

Dr. Eugene P. Cassidy, M.D., Medical
Director/Responsible Head
Marshalltown Medical & Surgical Center
3 South 4th Avenue
Marshalltown, Iowa 50158

Ref.# - KAN-97-05

Dear Dr. Cassidy:

During an inspection of your licensed hospital blood bank facility, conducted on November 20 to 25, 1995, a Food and Drug Administration Investigator from this office documented violations of Sections 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act, and Title 21, Code of Federal Regulations, Parts 600-680. The deviations found include, but are not limited to, the following:

Failure to maintain and/or follow adequate written standard operating procedures (SOPs) [21 CFR 606.100(b)] in that:

There is no SOP covering Quality Assurance in the performance and documentation of significant manufacturing steps, record review, or quality control.

There is no SOP to cover the invalidation of a viral disease marker test run.

Your SOP for Equipment Quality Control lists incorrect storage temperatures for Platelets and testing reagents.

There is no SOP covering blood products found out-of-range of storage temperatures.

Failure to maintain concurrent, detailed and/or accurate records [21 CFR 606.160(a)] in that:

Viral disease marker testing is not being performed according to test kit instructions.

DISTRIBUTION:
Orig.: Addressee
bcc: LF; FF (1970358); HFA-224; HFM-610; HFI-35; DIB/IA Dept. of Health(via FOI); HFC-210; RRS; HFR-SW400 (Breen); R3RF;

The documentation for viral disease marker testing is incomplete.

Failure to review all records pertinent to a unit of blood or blood component prior to the release or distribution of the final product [21 CFR 606.100(c)] in that:

Editing of documents does not always leave the material legible, dated, and initialed by the person responsible for making the changes.

The above violations are not intended to be an all-inclusive list of the deficiencies at your facility. At the conclusion of the inspection Form FDA 483, Inspectional Observations, was issued to and discussed with you. It is your responsibility as Responsible Head to assure that your establishment is in compliance with all requirements of the federal regulations.

Prompt action should be taken to correct the violations. Failure to promptly correct the violations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

cc: Robert Cooper, Chief Executive Officer
Marshalltown Medical & Surgical Center
3 South 4th Avenue